

Manufacturer/Importer Authorisation^{1, 2}

1. Authorisation Number 271/0637/22
2. Name of authorisation holder Sciencepharma Sp. z o.o. (ORG-100001975 / LOC-100002407)
3. Address(es) of manufacturing site(s) Sciencepharma Sp. z o.o. (ORG-100001975 / LOC-100002407), Ul. Chelmska 30/34, Warsaw, 00-725, Poland
Sciencepharma Sp. z o.o. (ORG-100001975 / LOC-100091320), Ul. Chocianowicka 70a, Lodz, 93-460, Poland
- 3.a Additional details on units inspected of manufacturing site(s) address(es)
4. Legally registered address of authorisation holder Ul. Chelmska 30/34, Warsaw, 00-725, Poland
5. Scope of authorisation and dosage forms² ANNEX 1 and/ or ANNEX 2
6. Legal Basis of authorisation Art. 40 of Directive 2001/83/EC
Art. 61 of Regulation (EU) No 536/2014
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation confidential
8. Signature
9. Date 2025-05-09
10. Annexes attached Annex 1 and/or Annex 2
Optional Annexes as required:
Annex 3(Addresses of Contract Manufacturing Site(s))
Annex 4(Addresses of Contract laboratories)
Annex 5(Name of Qualified Person)
Annex 6(Name of responsible persons)
Annex 7(Date of inspection on which authorisation granted, scope of last inspection)
Annex 8(Manufactured/ imported products authorised)³

¹ The authorisation referred to in paragraph 40(1) of Directive 2001/83/EC as amended and Article 88(1) of Regulation (EU) 2019/6, shall also be required for imports coming from third countries into a Member State.

²Guidance on the interpretation of this template can be found in the Interpretation of the Union format for Manufacturer/Importer Authorisation.

³The Competent Authority is responsible for the appropriate linking of the authorisation with the manufacturer's application (Article 42(3) of Directive 2001/83/EC as amended and Article 90(3) of Regulation (EU) 2019/6).

SCOPE OF AUTHORISATION

ANNEX 1

Name and address of the site: Sciencepharma Sp. z o.o., Ul. Chelmska 30/34, Warsaw, 00-725, Poland

Additional Details:

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS(according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS(according to part 2)

Part 1 - MANUFACTURING OPERATIONS

1.1 Sterile products

1.1.3 Batch certification

1.2 Non-sterile products

1.2.2 Batch certification

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

2.2 Batch certification of imported medicinal products

2.2.1 Sterile products

2.2.1.1 Aseptically prepared

2.2.1.2 Terminally sterilised

2.2.2 Non-sterile products

2.2.3 Biological medicinal products

2.2.3.6 Human or animal extracted products

2.3 Other importation activities

2.3.4 Other: distribution(en)

SCOPE OF AUTHORISATION

ANNEX 2

Name and address of the site : Sciencepharma Sp. z o.o., Ul. Chelmska 30/34, Warsaw, 00-725, Poland

Additional Details:

Human Investigational Medicinal Products
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Authorised Operations

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

2.2	Batch certification of imported medicinal products
	<i>2.2.1 Sterile products</i> 2.2.1.1 Aseptically prepared
	<i>2.2.2 Non-sterile products</i>
	<i>2.2.3 Biological medicinal products</i> 2.2.3.5 Biotechnology products 2.2.3.6 Human or animal extracted products
2.3	Other importation activities
	2.3.4 Other: distribution(en)

SCOPE OF AUTHORISATION

ANNEX 1

Name and address of the site: Sciencepharma Sp. z o.o., Ul. Chocianowicka 70a, Lodz,
93-460, Poland

Additional Details:

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS_(according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS_(according to part 2)

Part 1 - MANUFACTURING OPERATIONS

1.4	Other products or manufacturing activity
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	1.4.3 Other: storage _(en)
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Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

2.3	Other importation activities
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	2.3.1 Site of physical importation
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	2.3.2 Importation of intermediate which undergoes further processing
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**Any restrictions or clarifying remarks related to the scope of these Importation operations
(for Public users)**

Point 2.3.2 Importation of intermediate which undergoes further processing: Powder for dispersion
for infusion in primary packaging.

SCOPE OF AUTHORISATION

ANNEX 2

Name and address of the site : Sciencepharma Sp. z o.o., Ul. Chocianowicka 70a, Lodz,
93-460, Poland

Additional Details:

Human Investigational Medicinal Products
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Authorised Operations

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

2.3	Other importation activities
	2.3.1 Site of physical importation